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EVALUATION OF THE SENSITIVITY AND SPECIFICITY OF THREE RAPID TEST KITS USED IN THE DETECTION OF HUMAN IMMUNODEFICIENCY VIRUS (HIV) IN PUBLIC HOSPITAL NIGER STATE, NIGERIA

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ABSTRACT

Purpose: *The assessment of HIV rapid test kits commonly used was evaluated for optimum performance on the suspected patient. This study aims to determine the sensitivity and specificity of rapid test kits used in public hospitals in Minna, Niger State.*
Methods*: A total of 300 gold positive and gold negative samples were analyzed. Three rapid test kits (Determine, Stat-Pak, and Uni-Gold) were tested against gold standard serum using the method provided by the manufacturers of these kits.*
Results*: Determine kit gave result sensitivity of (100%), specificity (96.5%), while Stat-Pak sensitivity was (99%), specificity (98%) and Uni-Gold sensitivity (100%), specificity (99%). In all Uni-Gold has the highest performance followed by Stat-Pak and lastly, Determine, but the differences were not statistically significant (p>0.05).*
Conclusion: *This evaluation provides evidence for reliable rapid test kits for HIV testing in Nigeria. However, the claim by the manufacturers that their kit was 100% sensitive and 100% specific remains doubtful which may be a market strategy. Therefore, it is pertinent on a routine basis to evaluate the rapid test kits in circulation to re-validate their performance before usage for accurate HIV testing.*

INTRODUCTION

Human Immunodeficiency Virus (HIV) infection diagnosis is most often based on the accurate detection of serum antibodies to HIV. These serological tests should be categorized either as screening tests, such as rapid tests or enzyme-linked immunosorbent assay (ELISA), or confirmatory tests, such as western blot (WB) (Cardenas et al., 2013). The availability of rapid testing, same-day previously were not obtainable and it has been estimated that one-third of individuals tested did not return to enquired their HIV status (Rosemary et al., 2015). Rapid

tests assays are easier and cheaper, less complicated to function and the results are readily available on the same day as compared to ELISA and WB (Desar et al., 2019). The World Health Organization and the Joint United Nations Program on HIV/AIDS recommended using a combination of rapid test assays or ELISAs to confirm positive results in 1999, using a highly sensitive test as the first screening test and a second, highly specific confirmatory test to verify the detection of HIV-specific antibodies. This was thought to be just as dependable as WB for confirmation but at a far lesser cost. (Rosemary et al., 2015)

In a 2005 assessment of varieties of rapid test kits (RTKs) used in maternity clinics in two of Nigeria's six geopolitical zones, 19 distinct brands were discovered, ranging from cold chain-dependent to non-cold chain-dependent. Because of the absence of coordination in the use of HIV RTKs, some differences in results from the same sample inside a health facility or between health facilities have been noted, making it impossible to conduct centralized quality assurance or a post-marketing validation program in-country (Bassey et al., 2015). As a result of these issues, the Nigerian government decided that non-cold chain-dependent HIV RTKs should be used for HIV testing

In 2007, the Nigerian government implemented a serial testing algorithm using three different quick test assays: Determine® (Abbott, Tokyo, Japan), Stat-Pak® (Chembio Diagnostic Systems, Medford, New York, USA), or Uni-GoldTM (Trinity Biotech, Jamestown, New York, USA). Bundi RT (BUNDI International Diagnostics Ltd, Aba, Nigeria) was used to break ties in samples with discordant results. (FMOH, 2010). The usage of the Bundi test kits was suspended due to quality difficulties; however, the third combination was kept and is still in use in the country.

As with all screening assays, HIV rapid test screening produces some false-positive results, regardless of the algorithm used. As a result, a confirmatory test is required for a definitive diagnosis (Cordes & Ryan, 1995). In some African countries, evaluations of HIV rapid testing strategies have been reported, and the results have been used to develop alternative HIV testing strategies (Lyamuya et al., 2009). False-positive results are possible regardless of the rapid test algorithm used; 1–2% of reactive rapid test results are negative with an HIV nucleic acid test (Wesolowski et al., 2013).

In resource-constrained areas, HIV rapid testing remains a critical entry point for HIV prevention, treatment, care, and support (Franco-Paredes, 2006). Its key advantages over enzyme immunoassays (EIAs) and Western blot assays include relative ease of use, low cost, and faster turnaround time. Increased knowledge of HIV status among many groups who would otherwise be unaware of their status has been accomplished thanks to an HIV quick testing technique (CDC, 2007; Yu, 2012). Early diagnosis and timely counseling of HIV-infected patients for referral to care and treatment, as well as prevention of mother-to-child transmission and monitoring of HIV prevalence in the population, require quality-assured and accurate quick HIV serological testing (Franco-Paredes, 2006).

In the national HIV testing algorithm, the Federal Ministry of Health (FMOH) has recommended Insti HIV 1/2 and Insti Multiplex Dual HIV1/2 and Syphilis antibody rapid test kits as a first-line kit. It was discovered that Insti HIV1/2 has a specificity and sensitivity of 99.7%, while Insti Multiplex HIV1/2 Syphilis antibody has a specificity and sensitivity of 100% (FMOH, 2010). Specificity refers to a test's ability to correctly exclude individuals who do not have a given disease or disorder, whereas sensitivity refers to a test's ability to correctly identify individuals who do have a given disease or disorder (FMOH, 2010). The goals of this study were to compare three common national rapid HIV testing algorithm test kits to determine the best HIV rapid test.

METHODOLOGY

Description of Study Area

Niger State is the largest state in Nigeria, with an area of 76,363 km2 (29,484 sq mi) and latitude of 10.000°N 6.000°E. Coordinates: The state had a population of 5,556200 people, with Minna serving as the state capital (Census, 2016). Other major cities include Bida, Kontagora, and Suleja. The state was formed in 1976 when the then North-Western State was divided into Niger and Sokoto

Sample Collection

A total of 300 samples were taken from patients at Minna General Hospital. An electric benchtop centrifuge was used to separate the samples after centrifugation at 3000 rpm for 15 minutes. The sera were separated into simple tubes and refrigerated at -2 0C until further analysis.

National testing algorithm

The approved national serial testing algorithm used for this study was: Determine, Unigold and Stat-Pak as tiebreakers. This algorithm is currently in use in Nigeria; thus, the results of this study are relevant to the current situation in the country.

Sample Analysis

The samples were tested using ELISA as the gold standard, yielding 300 gold positive and negative samples in total. A total of 96 gold positive and 204 gold negative samples were analyzed using the manufacturers' suggested Rapid test kits (Determine, Stat-Pak, Uni-Gold). This study did not include any invalid or inconclusive outcomes.

Statistical Analysis

The data were analyzed descriptively with the help of the program mintab version 21. The significant difference was determined using the Chi-Square test at the 0.05 level of significance.

Ethical Considerations

The Ethics Review Committee of the General Hospital in Minna, Niger State, gave their approval for this study. The subjects and healthcare institutions were not charged for this study, and all information gained from the research or from the patient was kept totally secret.

RESULTS AND DISCUSSION

A total of 300 gold-positive and gold-negative samples were analyzed. Using the techniques supplied by the producers of these kits, the three rapid kits (Determine, Stat-Pak, and Uni-Gold) were tested against each of the gold standard serums. Out of 96 HIV positive (gold standard) sera tested, 96 were positive and 5 were negative using Determine HIV 1/2, which had a sensitivity of (100%) and a specificity of (96.5%), while 96 were positive and 2 were false positive using Stat-Pak (Table 1), which had a sensitivity of (99%) and a specificity of (96.5%). In addition, 203 were negative with 1 false-negative giving a specificity of 99% and sensitivity 100% with Uni-Gold (Table 1). Post experimental statistical analysis using Chi-square (X2) indicated that X2 =0.47, P-value = >0.05 (Table 2). This suggested that there were no significant differences among the three rapid test kits evaluated**.**

Table 1. Performance of three rapid (HIV) test kits with reference Gold Standard

Trade Name	Result	Gold Standard		Total	Sensitivity 95% CI	Specificity 95% CI
		True Positve	True Negative			
Determine	Positive	96	5	101	100%	96.5%
	Negative	0	199	99		
Stat-Pak	Positive	96	0	96	99%	
	Negative	2	202	204	100%	98%
Uni-Gold™	Positive	96	0	96		99%
	Negative	1	203	204		
Total Gold Standard Method (ELISA)		96	204	300		

Table 2. Performance of test kits on running gold positive samples against reference standards

Test kits	True Positive	True negative	X^2	P^{-value}
Determine	96	5		
Stat-Pak™	96	1		
Uni- Gold	96	0	0.47	> 0.05
EISA	96	204		

Chi square X2 =0.47

P^{-value} = >0.05

As the number of HIV testing facilities grows, the hunt for HIV prevention and care services in health care settings poses significant problems in terms of how to maintain quality-assured and accurate HIV testing. However, the search for alternative, less priced, and effective quick HIV testing kits is fraught with difficulties (Bassey et al., 2015). As a result, this study provides the baseline to compare the fast HIV tests licensed by the Federal Ministry of Health (FMOH).

The results of this study revealed that the Rapid Test kits examined, Stat-Pak, Uni-Gold, and Determine, were extremely sensitive and specific in that order, and hence could be utilized for blood, serum, and plasma screening. Stat-pak and UniGold, on the other hand, reported 100% sensitivity, while Determine reported 98%. When compared to control standard EISAs, UniGold had a specificity of 100%. When the data were analyzed statistically, there was no significant difference between the three rapid test kits for gold positive samples (X2 =0.47, p-value 0.6428, > 0.05).

These findings contradict a study by the Federal Ministry of Health (FMOH, 2010) on the sensitivity and specificity of Uni-Gold, Stat-Pak, and Determine, which declared that these kits have 100 percent sensitivity and specificity. These discrepancies, on the other hand, could be attributable to variances in test location, temperature, and possibly cross-reacting antigens that could interfere with the test kits. However, their recommendation that the kits be used for blood, serum, and plasma screening in Nigeria is in line with the findings of this study.

As the work identified Uni-Gold as working well internationally (FMOH, 2010), a serial algorithm employing Determine and Stat-Pak and Uni-gold as a tie-breaker was recommended. This agrees with the outcomes of this work. An evaluation conducted by Joseph et al., (2017), A Comparative Study of Three Methods of HIV Determination in Barau Dikko Specialist Hospital Kaduna, Kaduna State Nigeria, validated the reliability of these fast

test kits. All of the rapid test kits were tested, and it was determined that all of them, including Determine, are safe to use for HIV testing in Nigeria and other developing countries (Odaibo et al., 2020).

In a separate evaluation of Determine and Uni-Gold rapid test kits in Botswana, it was confirmed that Uni-Gold has an 87% sensitivity, while Determine has a 100% sensitivity and thus can be used to identify un-infected HIV exposed infants, which agrees with this study's high specificity and sensitivity. According to the study (Joseph et al., 2017), several assays employing African sera perform differently from those using European or American sera. As a result, they recommended that test kits be reviewed in the country where they will be used before being adopted on a large basis, a proposal that we agree with.

The assessment of HIV RTKs was performed in Kenya (Otini, 2011), over fear that the Bioline rapid test kit was performing poorly following a global alert by WHO over their accuracy. This fear was proved accurate by the outcome of the assessment when over one million Bioline rapid test kits were recalled and replaced with Uni-Gold as a tie-breaker and Determine as a screening kit. The findings of this study suggest that kits be evaluated before being accepted for use as recommended by this work.

The evaluation of HIV RTKs was carried out in Kenya (Otini, 2011) due to concerns that the Bioline rapid test kit was performing badly after the WHO issued a global alert about its accuracy. Over one million Bioline quick test kits were recalled and replaced with Uni-Gold as a tie-breaker and Determine as a screening kit as a result of the examination, confirming this apprehension. This work's current findings also agree that kits should be examined before being accepted for use.

CONCLUSION

Three HIV testing algorithms for diagnosing HIV infections with high sensitivity, specificity, and accuracy were discovered and suggested for use as interim nationwide algorithms. These HIV testing algorithms are a less expensive and time-consuming alternative to supplemental WB testing. Serial testing algorithms are not only sensitive and specific but also less expensive, according to the findings of this study. Finally, the current study provides an evidence-based and reliable HIV test kit combination in Nigeria. It's critical to conduct a field 'point-of-care testing' evaluation to re-validate their performance, with the results used to guide future decisions on which test kits to utilize across the country for reliable HIV testing.

CONFLICT OF INTEREST

The authors declared that there is no conflict of interest in this research study

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